REASONS FOR DENYING THE PETITION

The Federal Circuit's unremarkable decision in this unusual and highly fact-specific case breaks no new ground. To the contrary, it is firmly rooted in the most long-established and fundamental principles of patent law as announced and consistently applied by this Court, by the Federal Circuit, and by that court's predecessor. It is *SmithKline's* position that would truly be revolutionary, for it would contravene all the following tenets.

First and foremost, the public is entitled to practice the subject matter of the prior art. "It is self-evident that on the expiration of a patent the monopoly created by it ceases to exist, and the right to make the thing formerly covered by the patent becomes public property." *Singer Mfg. Co. v. June Mfg. Co.*, 163 U.S. 169, 185 (1896). "[T]he patent laws preclude the patentee of an expired patent and all others . . . from recapturing any part of the former patent monopoly; for those laws dedicate to all the public the ideas and inventions embodied in an expired patent." *Scott Paper Co. v. Marcalus Mfg. Co., Inc.*, 326 U.S. 249, 256 (1945). A patent claim may not "remove existent knowledge from the public domain, or . . . *restrict free access to materials already available*." *Graham v. John Deere Co. of Kansas City*, 383 U.S. 1, 6 (1966) (emphasis added). In short, the patent statute's requirements of novelty and nonobviousness "express a congressional determination that the purposes behind the Patent Clause are best served by free competition and exploitation of either that which is already available to the public or that which may be readily discerned from publicly available material." *Bonito Boats, Inc. v. Thunder Craft Boats, Inc.*, 489 U.S. 141, 150 (1989). Here, if claim 1 of the '723 patent, as construed by the Federal Circuit, were

in fact valid, Apotex and everyone else in the United States would be prohibited from producing prior art paroxetine hydrochloride anhydrate disclosed in the '196 patent, which expired in 1992. That is because, as the courts below found, it is impossible to produce paroxetine hydrochloride anhydrate without also producing at least a trace amount of paroxetine hydrochloride hemihydrate. App. 19a. This is an untenable result, and the Federal Circuit's decision precludes it.

Second, it is also axiomatic that claims must be construed the same way for infringement as for invalidity. *Burr v. Duryee*, 68 U.S. 579, 581 (1863). As this Court has held, a patentee who has sought and obtained a broad construction of a patent claim cannot later narrow it in order to avoid anticipation. *Smith v. Hall*, 301 U.S. 216, 232 (1937). To prove its infringement case, SmithKline obtained a construction of claim 1 that defines its invention structurally down to the smallest unit of crystalline paroxetine hydrochloride hemihydrate—*i.e.*, a single, undetectable crystal or any aggregation of such crystals. App. 11a. It was this broad construction, urged by SmithKline, that led the Federal Circuit inevitably to a holding of inherent anticipation. *Id.* at 22a. A holding that claim 1 is not anticipated would destroy this necessary logical symmetry that is a mainstay of the patent laws.

Third, and as a corollary to the above, an old maxim of patent law states that that which infringes, if later, anticipates if earlier. *Peters v. Active Mfg. Co.*, 129 U.S. 530, 537 (1889); *Knapp v. Morss*, 150 U.S. 221, 228 (1893); *Miller v. Eagle Mfg. Co.*, 151 U.S. 186, 203 (1894). As Professor Chisum states, the essential standard for infringement and anticipation is the same: whether a given product or process incorporates all the characteristics (*i.e.*, limitations) used to define the

invention in the claim of a patent. 1 DONALD S. CHISUM, CHISUM ON PATENTS § 3.02[1] (2005). In this case, because claim 1 of the '723 patent claims crystalline paroxetine hydrochloride hemihydrate in any amount, detectable or not, Apotex's paroxetine hydrochloride anhydrate product was held to infringe the claim because, as the district court inferred based on theories advanced by SmithKline's experts, Apotex's product inevitably will contain some amount, detectable or not, of the hemihydrate. App. 20a. But because paroxetine hydrochloride anhydrate made according to the disclosure of the '196 patent also inevitably would have contained at least a trace amount of the hemihydrate, the '196 patent anticipates claim 1 of the '723 patent. *Id.* at 22a.

The principles discussed above are inviolate: no decision of this Court or of the Federal Circuit has ever repudiated them, explicitly or implicitly. Not *Tilghman v. Proctor*, 102 U.S. 707 (1881). Not *Eibel Process v. Minnesota & Ontario Paper Co.*, 261 U.S. 45 (1923). Not any of the court of appeals decisions that SmithKline says conflict with the Federal Circuit's decision in this case. Accordingly, SmithKline's claim of a conflict in the case law is not and cannot be correct. Pet. at 18.

Because SmithKline's position in this lawsuit is antithetical to the most basic principles of patent law, it is not surprising that not one of the 12 judges of the Federal Circuit dissented from the denial of SmithKline's request for rehearing *en banc*. App. 220a. In fact, *not a single judge* who has ever evaluated claim 1 under SmithKline's claim construction and infringement position has ventured the opinion that SmithKline can or should be able to effectively revive the expired '196 patent to prevent the public from making and selling public-domain anhydrate. Not a single

judge has agreed with SmithKline's argument that the same claim construction that led to a finding that Apotex infringes claim 1 somehow does not also lead to a finding that claim 1 is anticipated. This is, at root, an unremarkable case, with an unremarkable outcome that should be left undisturbed.

I. The Federal Circuit's decision is consistent with long-established law of inherent anticipation and presents no conflict with any decision of this Court.

The result in this case was mandated by the most basic principles of patent law and presents no conflict with prior decisions of this Court. This Court and the Federal Circuit have long held that a claim is invalid for anticipation if the scope of the claim is so broad as to encompass subject matter that is inevitably produced when one practices an expired patent or other prior art.

A. It has long been the law that a claim is invalid where its subject matter is inherent in the prior art, regardless of whether that subject matter was appreciated when the application for the patent was filed.

The Federal Circuit's decision is the latest in a long line of cases that find anticipation when the subject matter of the claim is inherent and inevitable in the prior art. The concept of the inevitable result as the hallmark of anticipation is illustrated by this Court's decision in *Foley v. United States*, 260 U.S. 667 (1923). There, the patent in suit claimed the use of "a vaporous or vapor-laden atmosphere" to reduce the level of retained solvent during the manufacture of gunpowder. On appeal, the patentee argued that, according to the laws of physics, the government's processes necessarily

would create the vapor-laden atmosphere of the patents, regardless of whether the government intended it or not. *Id.* at 676. This Court held that the same could be said of prior art processes and adjudged the patents to be "without justification," *i.e.*, anticipated. *Id.* at 676-77.

The Federal Circuit has held that a claim is invalid for anticipation not only where a property is inherent in the prior art but also where, as here, an ingredient is inherently and inevitably contained in the prior art:

> [The] same reasoning holds true when it is not a property, but an ingredient, which is inherently contained in the prior art. The public remains free to make, use, or sell prior art compositions or processes, regardless of whether or not they understand their complete makeup or the underlying scientific principles which allow them to operate. The doctrine of anticipation by inherency, among other doctrines, enforces that basic principle.

Atlas Powder Co. v. IRECO Inc., 190 F.3d 1342, 1348 (Fed. Cir. 1999); *see also Schering Corp. v. Geneva Pharm., Inc.*, 339 F.3d 1373, 1379-80 (Fed. Cir. 2003) (holding that inevitable production of the claimed metabolite upon consumption of the prior art drug rendered claim defining the metabolite *per se* inherently anticipated). *Atlas Powder* involved a claim to an explosive composition requiring "sufficient aeration," which was an inherent element in prior art blasting compositions. 190 F.3d at 1344. As noted, *Schering* involved a claim to a metabolite that was necessarily formed by carrying out the process disclosed in an expired patent. 339 F.3d at 1379-80. The claims at issue in these cases were held invalid because, as discussed above, the law does

not permit a patent claim to remove from the public domain subject matter of an expired patent or other prior art.

Contrary to SmithKline's contention (Pet. at 14), the law has never demanded that those skilled in the art must have recognized the inherent feature when the claimed invention was first made by others. In *W.L. Gore Associates, Inc. v. Garlock, Inc.*, 721 F.2d 1540 (Fed. Cir. 1983), *cert. denied*, 469 U.S. 851 (1984), one of the first decisions of the Federal Circuit after that court was established, the court invalidated the broadest of several claims to a process for stretching Teflon to produce a material with unique waterproofing properties (Gore-Tex or an early version of it). Citing this Court's decisions in *Ansonia Brass & Copper Co. v. Electric Supply Co.*, 144 U.S. 11 (1892), and *General Electric Co. v. Jewel Incandescent Lamp Co.*, 326 U.S. 242 (1945), the court held that operation of a previously patented machine was a "consistent and reproducible use" of the process defined by the claim, regardless of whether operators of the machine recognized the particular aspects of the process recited in the claim or the result achieved. 721 F.2d at 1548-49. To hold otherwise, the court said, would permit the patenting of "an old and unchanged process." *Id.* at 1549; *see also In re Shetty*, 566 F.2d 81, 86 (C.C.P.A. 1977) (noting that what "may be inherent is not necessarily known").

In cases after *Gore*, the Federal Circuit has consistently found inherent anticipation based on scientific evidence dating from after the patent application. In *Eli Lilly & Co. v. Barr Labs, Inc.*, 251 F.3d 955 (Fed. Cir. 2001) (analyzed as obviousness-type double-patenting), the court found inherency based on scientific knowledge developed long after the patent issued. 251 F.3d at 969-70. Likewise, in *Atlas Powder*, the inherent ingredient in the prior art composition

was established using evidence produced by tests conducted after issuance of the patent. And, most recently, in *Schering v. Geneva*, the court expressly rejected "the contention that inherent anticipation requires recognition in the prior art." 339 F.3d at 1377, *citing In re Cruciferous Sprout Litigation*, 301 F.3d 1343, 1351 (Fed. Cir. 2002); *MEHL/Biophile Int'l Corp. v. Milgraum*, 192 F.3d 1362, 1366 (Fed. Cir. 1999) ("Where . . . the result is a necessary consequence of what was deliberately intended, it is of no import that the article's authors did not appreciate the result.").

In the face of this longstanding and consistent authority, SmithKline's claim that the Federal Circuit in the case at bar veered way off course and "vastly expand[ed]" the doctrine of inherent anticipation rings hollow. Pet. at 24. To the contrary, the truly revolutionary position is SmithKline's, for it would remove from the public domain subject matter of an expired patent.

B. There is no conflict with any decision of this Court.

There is also no conflict with any decision of this Court. To the extent that any general teaching can be derived from *Tilghman v. Proctor*, 102 U.S. 707 (1881), *Eibel Process v. Minnesota & Ontario Paper Co.*, 261 U.S. 45 (1923), or *Carnegie Steel Co. v. Cambria Iron Co.*, 185 U.S. 403 (1902), it is that *accidental results*, obtained "in pursuit of other and different results," do not constitute anticipation. *Tilghman*, 102 U.S. at 711.

First, in each case there was an absence of proof that any of the prior art processes or machines *ever* duplicated the subject-matter of the patent claims in issue. *See Tilghman*, 102 U.S. at 711-12 ("We do not regard the accidental

formation of fat acid in Perkin's steam cylinder . . . (*if* the scum which rose on the water issuing from the ejection pipe was fat acid) as of any consequence. . . ." (emphasis supplied)); *Eibel*, 261 U.S. at 66 ("In the first place we find no evidence that any pitch of the wire, used before Eibel, had brought about such a result . . . and in the second place *if* it had done so under unusual conditions, accidental results, not intended and not appreciated, do not constitute anticipation." (emphasis supplied)); *Carnegie*, 185 U.S. at 429 (failure of proof that prior art process incorporated the patented process). *See generally Schering*, 339 F.3d at 1378 ("In contrast to the present case, the record in *Eibel* and *Tilghman* did not show that the prior art produced the claimed subject matter.") The passages in these cases that SmithKline relies on are couched in the hypothetical. Pet. at 11-13. The decisions themselves simply do not address situations where, as here, the prior art reference naturally and inevitably contains or produces the subject-matter of the patent claim.

Second, if subject matter is naturally and inevitably produced by the prior art, then it cannot be said to have been accidental—anymore than the natural occurrence of rain can be said to be accidental. *See Ecolochem, Inc. v. Southern Cal. Edison Co.*, 863 F. Supp. 1165, 1179 n.17 (C.D. Cal. 1994) (natural and necessary consequence of a prior art process cannot be considered to be an accident), *aff'd in part, rev'd in part on other grounds*, 1996 U.S. App. LEXIS 13330 (Fed. Cir., June 5, 1996), *cert. denied*, 532 U.S. 974 (2001). In the case at bar, an ordinarily skilled chemist seeking to make the paroxetine hydrochloride of the '196 patent does not "accidentally" make paroxetine hydrochloride containing at least a trace amount of hemihydrate; he or she *inevitably* makes it.

Indeed, evidence in the record shows that far from being accidental, the production of paroxetine hydrochloride hemihydrate was not unexpected when the application for the '723 patent was filed. This was recognized by Ian Lynch, a SmithKline chemist, who testified at deposition in the case at bar that polymorphism of organic compounds was a known phenomenon that "has been documented historically for many, many years" and "should not come as a surprise." This deposition was put into evidence at trial. (Lynch Dep. 236:22 to 237:2, 237:5 to 238:17, 238:20 to 239:19, Tr. at 213:11-13, Pretrial Order at Ex. 43). Further, in a 1985 memorandum, Lynch noted that "[p]olymorphism should be treated as a guilty until proven innocent situation"—meaning polymorphism was the rule rather than the exception. (DTX 178 at 5). Lynch was undoubtedly a person of ordinary skill in the art, and to him, the production of polymorphs such as the hemihydrate was no accident.

Third, neither *Tilghman*, *Eibel*, nor *Carnegie* permitted the patentee to exclude the public from practicing the subject matter of the prior art. That is precisely what SmithKline is trying to do here, but none of this Court's or the Federal Circuit's case law authorizes such a perverse result.

C. SmithKline's other authority is not on point.

SmithKline relies heavily on two cases involving the antibiotic tetracycline to support its argument that the unrecognized emergence of trace quantities of PHC hemihydrate in its production of PHC anhydrate cannot be held to inherently anticipate claim 1 of its '723 patent. But in neither case was the issue of § 102 anticipation litigated.

In re Coordinated Pretrial Proceedings in Antibiotic Antitrust Actions, 498 F. Supp. 28 (E.D. Pa. 1980), *aff'd*, 676 F.2d 51 (3d Cir. 1982) (Pet. at 19), involved a suit by the government against Pfizer for cancellation of its patent on tetracycline on the ground that Pfizer's representatives committed fraud on the Patent Office. The district court held that Pfizer's failure to inform the examiner that trace amounts of tetracycline were produced in the manufacture of the prior art aureomycin did not constitute fraud, a holding the Third Circuit affirmed. *State of North Carolina v. Chas. Pfizer & Co.*, 384 F. Supp. 265 (E.D.N.C. 1974) (Pet. at 19), is a companion antitrust case decided the same way. Neither court gave any consideration to the claims of the patent, and, indeed, both decisions appear to have been based on an assumption that the invention of the patent was a clinically useful quantity of tetracycline, not the trace amount that was found in the prior art aureomycin.

SmithKline's other "co-production" cases are no better. *Ritter v. Rohm & Haas Co.*, 271 F. Supp. 313 (S.D.N.Y. 1967) (Pet. at 18), involved a patent on a chemical process, not on a previously unrecognized chemical compound. The court held that a prior art patent on a different process that, if carried out under a specific set of conditions, would produce the same product as the patentee's process, did not anticipate. *Ritter* thus stands for the proposition that only *inevitable* results, not chance or accidental results, can anticipate a patent claim. In *In re Seaborg*, 328 F.2d 996 (C.C.P.A. 1964) (Pet. at 19-20), the court reversed the Patent Office's rejection of claims to a newly discovered isotope of uranium as inherently anticipated by a prior patent on a nuclear reactor and its operation. The C.C.P.A.'s opinion reflects considerable doubt as to whether operation of the reactor in fact produced the claimed isotope.

Also inapplicable are *Rosco, Inc. v. Mirror Lite Co.*, 304 F.3d 1373 (Fed. Cir. 2002), and *Silvestri v. Grant*, 496 F.2d 593 (C.C.P.A. 1974) (Pet. at 14, 14 n.5). These cases concern anticipation in the context of prior invention under § 102(g), under which recognition by the inventor has long been necessary to establish conception and reduction to practice. *Rosco*, 304 F.3d at 1381; *Silvestri*, 496 F.2d at 597. While *Rosco* also includes a discussion of inherent anticipation, its holding on that point was based on the lack of evidence that the allegedly inherent feature of the invention was inevitably present in the prior art reference. *Rosco*, 304 F.3d at 1380-81.

While language in some other Federal Circuit decisions can be interpreted as suggesting a recognition requirement in the doctrine of inherent anticipation, *see, e.g., Continental Can Co. USA, Inc. v. Monsanto Co.*, 948 F.2d 1264 (Fed. Cir. 1991) (Pet. at 14), the Federal Circuit has since recognized that "*Schering Corp. v. Geneva Pharm., Inc.* has clarified any confusion on this score." *Toro Co. v. Deere & Co.*, 355 F.3d 1313, 1320 (Fed. Cir. 2004). Thus, it is not surprising that not a single Federal Circuit judge dissented from the order denying *en banc* review in this case. App. 220a. The law governing this appeal is settled, and there is no need for this Court's review.

II. The Federal Circuit's decision does not discourage innovation.

SmithKline's attempt to portray this case as "important" because the Federal Circuit's decision threatens existing patents and will chill innovation (Pet. at 21-22) is based on a wholly erroneous premise. The Federal Circuit did not invalidate the entire '723 patent on paroxetine hydrochloride hemihydrate. App. 22a. The court invalidated a single broad

claim that, if allowed to stand, would have prevented others from practicing the prior art. *Id.* It is a well-known principle among patent claim drafters that the broader the claim, the more susceptible the claim is to read on the prior art. Thus, patent attorneys routinely include in a patent application a series of claims of different format and scope. According to the leading text on claim drafting, "[s]ome claims should be sufficiently detailed that even if the broad claims covering the inventor's concept are held invalid, anyone who copies any of the inventor's disclosed preferred embodiments will infringe a valid detailed claim." ROBERT FABER, LANDIS ON MECHANICS OF PATENT CLAIM DRAFTING § X-2 (5th ed. 2001).

SmithKline's skilled drafters did just that with claims 2 through 6 of the '723 patent, which were unasserted in this lawsuit and remain fully in force. App. 192a. These additional claims are considerably narrower than claim 1. They define, for example, crystalline paroxetine hydrochloride hemihydrate "in substantially pure form"; or "[a]n anti-depressant pharmaceutical composition comprising an effective anti-depressant amount of crystalline paroxetine hydrochloride hemihydrate and a pharmaceutically acceptable carrier"; or "[a] method of treatment of depression in mammals, which method comprises administering an effective amount of crystalline paroxetine hydrochloride hemihydrate." *Id.* These claims effectively preclude the public from making, using, or selling the hemihydrate in any useful amount. They remain valid.

The use of proper claim drafting techniques to avoid inherent anticipation in cases like this one, where an inventor claims to have discovered a previously unrecognized constituent of a known product, is illustrated by *In re Kratz*, 592 F.2d 1169, 1174 (C.C.P.A. 1979) (claims to a chemical flavoring agent not invalid for inherent anticipation because they did not claim either

the chemical in its naturally occurring state as a constituent of strawberries or strawberries *per se*, but rather claimed a substantially pure, synthetically produced version of the chemical); and *In re Bergstrom*, 427 F.2d 1394, 1401-02 (C.C.P.A. 1970) (claims to pure prostaglandin compounds extracted from sheep glands not inherently anticipated by either the naturally occurring compounds themselves or prior art extracts; inventors have not "claimed sufficiently broadly to encompass, what has previously existed . . . in nature's storehouse"). *See also Schering*, 339 F.3d at 1381 (discussing claim drafting techniques, citing *Kratz* and *Bergstrom*).

SmithKline calls the inherent-anticipation issue "recurring." Pet. at 21. If it is so, that is only because of a fad among some drug companies to obtain patents on some aspect of a previously marketed drug that include claims that can be used to try to block generic competitors whose drug products are based on expired patents. *See, e.g., Schering*, 339 F.3d 1373 (claims in patent on metabolite of marketed drug Claritin® held invalid for inherent anticipation); *In re Buspirone Patent Litigation*, 185 F. Supp. 2d 340, 359 (S.D.N.Y. 2002) (claims to method of administering metabolite of buspirone would be inherently anticipated if construed to cover administration of buspirone itself); *In re Omeprazole Patent Litigation*, 2001 U.S. Dist. LEXIS 7103 (S.D.N.Y. May 31, 2001) (claims to metabolite of Prilosec®; same analysis); *Eli Lilly*, 251 F.3d at 970-72 (claims on method of blocking "serotonin up-take" by administering Prozac® held invalid for obviousness-type double patenting based on earlier patent on Prozac®). If the Federal Circuit's decision discourages such abusive uses of the patent system, then the public interest will be served.

Last, SmithKline asserts at several points in its petition that patents are granted for contributions to the fund of human

knowledge, implying that its discovery of paroxetine hydrochloride hemihydrate entitled it to a patent. Pet. at 4, 16. This is too simplistic. Advances in human knowledge, however important, receive the reward of a patent only if they constitute patentable subject-matter under 35 U.S.C. § 101, and then only if they pass the tests of anticipation under § 102 and nonobviousness under § 103. *Titanium Metals Corp. of America v. Banner*, 778 F.2d 775 (Fed. Cir. 1985); *In re Cruciferous Sprout Litigation*, 301 F.3d 1343 (Fed. Cir. 2002), *cert. denied*, 538 U.S. 907 (2003). The subject matter defined by claim 1 of the '723 patent did not pass the test.

III. If the Court grants the writ, then review of other issues will be required.

In this Court, a prevailing party may defend the judgment on any ground that was raised below. *Granfinanciera, S.A. v. Nordberg*, 492 U.S. 33, 38 (1989). If the Court were to grant SmithKline's petition, we respectfully suggest that, in order to do justice between the parties, the Court would then be obliged to consider all the grounds that the district court and the Federal Circuit have advanced for Apotex prevailing, including:

- whether the Federal Circuit correctly construed claim 1 of the '723 patent;
- whether the evidence supported an inference of infringement under the single-crystal claim construction;
- whether claim 1 should have been held invalid because it violates the public-use bar of 35 U.S.C. § 102(b); and
- whether claim 1 should have been held invalid for indefiniteness.

CONCLUSION

For all the above reasons, the petition for certiorari should be denied.

Respectfully submitted,

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IN THE

Supreme Court of the United States

SMITHKLINE BEECHAM CORPORATION, SMITHKLINE BEECHAM P.L.C., GLAXOSMITHKLINE, P.L.C., AND BEECHAM GROUP, PLC,

Petitioners,

v.

APOTEX CORPORATION, APOTEX, INC. AND TORPHARM, INC.,

Respondents.

On Petition for a Writ of Certiorari to the United States Court of Appeals for the Federal Circuit

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INTRODUCTION

The United States acknowledges that the Federal Circuit has established the following legal rule: A compound that is inevitably produced by prior art is inherently anticipated (and thus not patentable) *even if no person skilled in the art previously recognized that the product existed.* US Br. 6, 9. The United States defends this legal rule as consistent with patent law and this Court's precedent and urges this Court to deny the petition. The United States is wrong.

The United States first argues that the Federal Circuit's rule is consistent with undisputed and inapplicable case law holding that a *characteristic* of a pre-existing product is not patentable even if no one previously recognized that characteristic. A newly discovered *product* unrecognized in the prior art has never been treated as a *characteristic* of a pre-existing product, see *General Elec. Co.* v. *Jewel Incandescent Lamp Co.*, 326 U.S. 242, 247 (1945), whether inevitably produced or not. Instead, this Court and others have routinely recognized that inherent anticipation does not apply when the prior art accidentally produces the subsequently claimed product. Indeed, although the United States refuses to acknowledge it, this Court expressly held that "it would be *absurd* to say" that "accidental[]" or "unwitting" results could constitute "anticipation of [a later] discovery." *Tilghman* v. *Proctor*, 102 U.S. 707, 712 (1880) (emphasis supplied). The United States' strained, unpersuasive attempts to distinguish this Court's contrary case law reveal that its proposed legal rule is a significant departure from precedent. Unrecognized products do not anticipate later patent claims by the inventors who discover those products.

Granting patent rights to those who discover previously unrecognized products rewards deliberate inventive activities. In contrast, the rule proposed by the United States would discourage investment in discovery and invention, because

any discovery might have existed in unrecognizable trace amounts in the prior art, and patents based on that discovery would forever be subject to post hoc invalidation as new products are discovered. The new rule would also result in the invalidation of extant patents on the same theory. See App. 59a (Newman, J., dissenting). The United States simply ignores Judge Newman's dissenting view and the views of patent law experts such as Professor Chisum.

In addition, the United States argues that the rule urged by petitioner – that inherent anticipation does not invalidate a patent if the prior art accidentally produces the newly claimed product – would remove prior art from the public domain. This is wrong here and as a general matter. As the United States acknowledges, the district court found "that PHC hemihydrate was *not* inherent in PHC anhydrate because it is possible that practicing the '196 patent in a non-seeded laboratory would not have produced any PHC hemihydrate." US Br. 3 (emphasis supplied) (citing App. 132a-133a). Accordingly, the hemihydrate was *not* originally a co-product of the prior art. It was the "seeding" that occurred where the anhydrate was produced that resulted in the conversion of the anhydrate to the hemihydrate, *id.* (citing App. 129a-130a), not the practice of prior art. Apotex is not practicing the prior art.

More generally, there are ways to protect truly innocent parties practicing the prior art, such as mitigation of damages, see *Embrex, Inc.* v. *Service Eng'g Corp.*, 216 F.3d 1343, 1353 (Fed. Cir. 2000) (Rader, J., concurring), or through the creation of an equitable defense, as has occurred in other jurisdictions. See *Gillette Safety Razor Co.* v. *Anglo Am. Trading Co.*, (1913) 30 R.P.C. 465. It is for *this Court* to decide how to address the treatment of prior art in connection with a claim based on discovery of a previously undetected product. The Federal Circuit may not simply disregard this Court's precedent teaching that recognition is required for prior art to anticipate and invalidate a subsequent claim.

ARGUMENT

It is undisputed that patent protection applies to novel inventions and that a claimed invention is anticipated by prior art if all elements of the invention are expressly or inherently described in the prior art. But, the precise issue here is what is required for a product to be inherently described in the prior art. Under this Court's precedent, there are two requirements: (i) the missing subject matter is necessarily present in what is expressly described in the prior art, *and* (ii) a person of ordinary skill in the art would recognize this. See *Tilghman* v. *Proctor*, 102 U.S. 707 (1881); *Eibel Process Co.* v. *Minn. & Ont. Paper Co.*, 261 U.S. 45 (1923); *Carnegie Steel Co.* v. *Cambria Iron Co.*, 185 U.S. 403 (1902). Where the presence of the process or product is necessarily present in the prior art, but unrecognized, that process or product has *not* been deemed anticipated. Instead, it is characterized as "accidental" or "unappreciated," and does not bar a new patent under § 102. See also Pet. 6 & n.2.

The United States, however, claims that the sole requirement of inherent anticipation is the "necessarily present" prong. Thus, the legal rule urged by the United States eliminates the second prong of this Court's test for inherent anticipation – the requirement that an undetected product be recognized or recognizable by one skilled in the art. This outcome would eviscerate *Tilghman* and its progeny. None of the authority the United States cites supports its proposed rule.

A. The United States first relies on *General Electric* and other authority holding that "[i]t is not invention to perceive that the product which others had discovered had qualities they failed to detect," 326 U.S. at 248-49, even when those qualities are unrecognized by those skilled in the art. The cases cited (like the similar line of cases addressed in petitioners' Reply Br. 3-4) stand only for the unexceptional proposition that unappreciated *characteristics and qualities* of products and processes described in the prior art are

inherently anticipated. This line of cases does not apply when a separable product is unrecognized, as opposed to a mere feature of the patented product.

The United States disparages petitioners' distinction of the case law, calling it a distinction without a difference. See US Br. 12. But, critically, in every cited case finding inherent anticipation based on a characteristic, that characteristic has been a quality or feature of the patented product or process at issue, not a separable and distinct product. See *General Elec.*, 326 U.S. at 247 (strength); *Atlas Powder Co.* v. *IRECO Inc.*, 190 F.3d 1342 (Fed. Cir. 1999) (aeration); *In re Cruciferous Sprout Litig.*, 301 F.3d 1343, 1349 (Fed. Cir. 2002) (glucosinolate level); *Titanium Metals Corp. of Am.* v. *Banner*, 778 F.2d 775, 780 (Fed. Cir. 1985) (corrosion-resistance). The United States cites no case finding that an undetected product of the prior art is a "characteristic" of that prior art rather than a separable discovery under § 102 of the Patent Act. Indeed, as shown in the Petition and Reply, until recently, established case law did not find inherent anticipation without recognition.[1]

B. Like respondent, the United States strains to distinguish this Court's precedent, holding that the doctrine of inherent anticipation does not apply if the prior art accidentally or unwittingly presents the claimed subject matter. But, in *Tilghman*, this Court said:

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[1] Plainly, hemihydrate is not a "characteristic" of anhydrate, but a completely different product. As the district court explained, polymorphs are chemical compounds that have different three-dimensional structures, dramatically affecting their properties. App. 115a. For example, diamond and graphite consist of carbon atoms, with differing arrangements that result in significantly different properties. *Id.* Diamond is not an inherent characteristic of graphite simply because both are crystalline forms of carbon; and unrecognized traces of diamond dust in graphite should not preclude a patent to the later discoverer of diamonds. Similarly, undetected trace amounts of hemihydrate in anhydrate should not preclude its later patentability.

> [i]f the acids were accidentally and unwittingly produced, whilst the operators were in pursuit of other and different results, *without exciting attention and without its even being known what was done or how it had been done*, it would be *absurd* to say that this was in anticipation of Tilghman's discovery. [102 U.S. at 711-12. (emphasis supplied).]

Eibel Process involved a patent on a machine. Again this Court held that "accidental results" of prior art that are "not intended and not appreciated, do not constitute anticipation." 261 U.S. at 66.

The United States treats these words as meaningless and searches for purported distinctions. Initially, the United States says that this Court's cases did not involve "attempts to patent pre-existing products." US Br. 16. Neither does this case. The anhydrate was pre-existing, but the patent claims the hemihydrate. Further, the prior art (the '196 patent) does not describe hemihydrate; the district court labeled any such contention "frivolous." App. 131a.

Nor can the cases be distinguished as involving process patents rather than product patents. US Br. 16. Nothing in this Court's discussion suggests that the recognition requirement is limited to process cases. None of the treatises, commenters, or cases adopting the recognition requirement has thought it limited to process patents. Indeed, the most notable examples of the application of accidental prior use involved product patents – specifically, the cases involving the accidental, unrecognized production of tetracycline in connection with the production of Aureomycin, and *In re Seaborg*, discussed in detail in the Petition at 19 and the Reply Brief at 5-6.

In any event, the claimed invention in *Eibel Process* was an apparatus and thus a new product, not a new process. The inventor in *Eibel Process* sought to patent an improved machine, even though those improvements had existed in two

prior devices without recognition. 261 U.S. at 66. This Court nonetheless found that the new product was not inherently anticipated by the prior art machine, and cited *Tilghman*'s reasoning to support its conclusions.

The United States' attempt to distinguish this Court's cases as involving processes, not products, simply does not withstand scrutiny. In each case, the Court sought to reward deliberate inventive activities and provide incentives to study existing products and processes for improvements. This rationale is no less important for products than for processes.

The United States also half-heartedly defends the Federal Circuit's attempted distinction of contrary precedent, particularly *Tilghman*, noting that it was "unclear in the cases relied on by petitioners whether the practice of the prior art had actually produced the allegedly inherent result." US Br. 17. But in *Tilghman*, there was evidence that the prior art process did produce the desired fat acids. See, *e.g.*, 102 U.S. at 711. Even leaving that point aside, an alleged lack of clarity is no reason to disregard the Court's express assumption that the prior art inevitably produced the newly claimed invention, followed by this Court's conclusion that the new invention was *not anticipated because it had not previously been appreciated*. See Pet. 12-17 (explaining why this reading of the Court's cases is not tenable). [2]

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[2] There is no record evidence that anyone obtained hemihydrate using the '196 patent process before the inventors of the hemihydrate patent. The district court explained that the hemihydrate "in all likelihood" did not exist in 1982 – years after the '196 patent was filed. App. 146a. *See id.* at 132a ("[t]he serendipitous appearance of a polymorph years after another polymorph of the same crystal is patented does not prove to the requisite degree of certainty that the new polymorph was inherent in the old"). The Federal Circuit *inferred* hemihydrate's presence in the prior art based on its inventors' later discovery. Thus, the evidence of the hemihydrate's existence in the prior art is no better, and arguably worse, that the evidence of the existence of the fat acids in prior art in *Tilghman*.

Finally, the United States claims that there is no confusion in the Federal Circuit's jurisprudence regarding inherent anticipation because the recognition requirement has been eliminated by *Schering* and this case. US Br. 18-19. Petitioners fully agree: The Federal Circuit has eliminated the conflict that existed among its earlier cases, essentially overruling *Continental Can Co. USA, Inc.* v. *Monsanto Co.*, 948 F.2d 1264 (Fed. Cir. 1991), and *In re Seaborg*, 328 F.2d 996 (C.C.P.A. 1964). And, because the Federal Circuit has the final word on patent law issues, the inconsistent authority set forth in the Petition and Reply no longer create a conflict. What these cases demonstrate, however, is that for a substantial time, this Court's precedents were read to require recognition of a product to find a new claim for that product invalid as inherently anticipated. This is clear not only in the case law, but in the treatises, model jury instruction and articles addressing accidental prior use and its impact on inherent anticipation. If all this authority is to be overruled, only this Court should do so.

C. The United States' willingness to jettison the recognition requirement and the associated doctrine of accidental prior use appears to be based on the fear that any other rule would result in the withdrawal of prior art from the public domain. Initially, if this is an unacceptable consequence of this Court's precedent, this Court must make that determination, not the Federal Circuit. In *Tilghman* itself, this Court held that the accused infringers could not produce the sought-after fat acid even though the fat acid had existed, albeit unrecognized, as a byproduct of the practice of the prior art. 102 U.S. at 711. ("[i]t is our opinion that . . . it is a valid patent, and that the defendants infringe it").

Moreover, there are competing interests at stake in this area of doctrine. A principal goal of patent law is "secur[ing] to the inventor the reward he deserves" if that invention "has advanced the art substantially." *Eibel Process*, 261 U.S. at 63. Another important goal is accumulation of public